

DEPARTMENT OF VETERANS AFFAIRS Veterans Health Administration Washington DC 20420

IL 10-2001-011

In Reply Refer To: 13B

July 18, 2001

UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

GUIDELINES FOR HIV TESTING IN VA FACILITIES FOLLOWING OCCUPATIONAL EXPOSURES

1. This information letter provides guidance concerning Human Immunodeficiency Virus (HIV) testing in occupational exposure situations; clarifies Department of Veterans Affairs (VA) policy about testing for HIV, and includes a collection of consensus recommendations of a Committee (see subpar. 2b) that included experts in the field of HIV, Acquired Immune Deficiency Syndrome (AIDS), and occupational safety.

2. Background

- a. Considerable progress has occurred toward the development of therapeutic agents used to treat HIV infected individuals and significant technical advancement has been made in diagnostic techniques to detect HIV. These recent advancements necessitated a re-examination of VA policies and procedures as related to testing for HIV within the context of potential occupational exposure.
- b. A committee was established to review existing VA policies on HIV testing in situations of potential occupational exposure. The Committee was composed of front-line HIV care providers including infectious disease experts, infection control and occupational health experts both from VA Central Office and the field; VA General Counsel's Office; the National Center for Ethics; and a union representative.
- c. The guidelines contained in this Information Letter represent a collection of recommendations of the Committee and provide reference to the United States (U.S.) Public Health Service (PHS) guidelines for management of occupational exposures and post-exposure prophylaxis to HIV.
 - d. The Committee addressed six specific areas. These include:
 - (1) VA HIV testing policy in occupational exposures in general;
- (2) Situations where the source patient refuses or is incapable of giving consent or an appropriate authorized surrogate refuses consent;
 - (3) Confidentiality issues related to exposed employees' records;
 - (4) Exposures during off-duty hours;

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- (5) Availability of state-of-the-art diagnostic technologies to detect HIV; and
- (6) Process integrity issues.

3. General Guidance for VA Facilities

a. The U.S. PHS has developed guidelines for the management of occupational exposures to HIV and made recommendations for post-exposure prophylaxis (see subpar. 9a). This information, designed as general guidance, can be used by all VA health care facilities in establishing appropriate programs for the management of health care workers (HCWs) who have occupational exposure to blood and other potentially infectious materials, and for post-exposure prophylaxis. This document is accessible on the web site:

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm.

4. A Reminder of VA Policy on HIV Testing

- a. VA policy provides that every patient has the right to informed participation in the patient's health care decisions (see subpar. 9b, VHA Handbook 1104.1, and Title 38 Code of Federal Regulations (CFR) §17.32, regarding Informed Consent). Public Law 100-322 Section 124, as amended, specifies that testing for HIV must be voluntary and requires specific written consent by the patient to be tested (see subpar. 9c). The law also provides that HIV testing be accompanied by documented pre- and post-test counseling.
- b. This Information Letter further clarifies VA policy about testing for HIV. A common query is whether specimen left over from other diagnostic or therapeutic tests may be tested for HIV when the source patient cannot be located, is incapacitated, or refuses the HIV test. Current law mandates that VA may administer a test to a patient that would lead to the diagnosis of HIV infection <u>only</u> with the prior written consent of the patient, or of an authorized surrogate in accordance with applicable law and regulations. This includes circumstances where occupational exposures have occurred.
- c. In situations of occupational exposures, there are instances where testing of the source patient is difficult or impossible. These situations include:
 - (1) Source patient or appropriate authorized surrogate refuses consent for HIV test.

Recommendation: Offer exposed employee post-exposure management and anti-retroviral prophylaxis, as warranted by PHS guidelines. The patient, or appropriate authorized surrogate may be re-approached by a different provider, e.g., a counselor, an attending physician or a nurse who is not involved in or affected by the exposure event. Careful attention needs to be taken to ensure that coercion is neither applied nor perceived when a person who initially declined testing is re-approached. If the patient, or appropriate authorized surrogate, still declines, testing may not be performed, even on available residual specimens.

(2) Source patient left VA medical center before consent was obtained.

Recommendation: Offer exposed employee post-exposure management and anti-retroviral prophylaxis, as warranted according to PHS guidelines. Follow-up with the patient to obtain consent. The source patient's written consent on VA Form 10-5345, Request for and Consent to Release of Medical Records Protected by 38 U.S.C. § 7332, (see subpar. 9d) is also required to disclose the HIV test results to the exposed employee. Provide assistance or support where possible to maximize patient's convenience in the consenting and testing process. A specimen previously collected for other purposes <u>cannot</u> be used for HIV testing without appropriate consent.

(3) Source patient cannot be located.

Recommendation: Offer exposed employee post-exposure management and anti-retroviral prophylaxis, as warranted according to PHS guidelines. Specimen previously collected for other purposes <u>cannot</u> be used for HIV testing without appropriate prior consent.

(4) Source patient is incapacitated, incompetent or comatose.

Recommendation: Offer exposed employee post-exposure management and anti-retroviral prophylaxis, as warranted according to PHS guidelines. VA regulations limit diagnostic testing of HIV and the disclosure of information related to HIV infection, when the patient lacks the decision-making capacity (incapacitated, incompetent, or comatose). Testing for HIV, like any other diagnostic or therapeutic procedure, typically requires the patient's (or appropriate authorized surrogate's) informed consent. When the purpose of the test is to confirm the patient's HIV status following an occupational exposure, a written consent allowing the test for HIV is required. Furthermore, disclosure of the test results to the exposed employee also requires written consent from the patient, or from the patient's legal guardian in instances where the patient lacks the decision-making capacity. Such disclosures require the specific written consent of the patient's court appointed legal guardian on VA Form 10-5345. If the patient is incompetent and there is no consenting court appointed legal guardian, HIV testing and disclosure of the HIV test results are not permitted.

(5) Source patient is deceased.

Recommendation: Offer exposed employee post-exposure management and anti-retroviral prophylaxis, as warranted according to PHS guidelines. If the purpose of testing at autopsy is to establish the diagnosis of HIV, then specific consent of the deceased's next-of-kin, or appropriate authorized surrogate, would be required (see subpar. 9e).

5. Employee Confidentiality and Record Keeping

a. Confidentiality of medical information pertaining to both HCWs and patients is essential. Employee health records should not be accessed by anyone other than Employee Health staff and others who are involved in providing health care to the exposed HCW without the prior written consent of the worker or as otherwise authorized by law. Appropriate security measures and sanctions must be in place to assure the confidentiality of all employees' health records.

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b. Medical records and HIV test results of patients who are identified as the potential source of exposure of blood and/or body fluids are subject to confidentiality protections imposed by law (see subpar. 9f). Test results or other information concerning a patient's HIV status may not be disclosed, in most instances, without the patient's specific prior written consent. The source patient's identity and HIV status <u>must not be recorded or reported</u> in HCW's records unless appropriate written permission is obtained.

6. Exposure Management During Non-administrative Work Hours

- a. A person can be designated within the facility to deal with issues on occupational exposure to blood and body fluids with coverage provided for off-duty hours.
- b. A number of the exposures to blood and body fluids occur off-shifts and during non-administrative hours. The written policies and procedures on the management of the HCW exposed during off-shift and non-administrative duty hours should be uniformly in accordance with the Exposure Control Program of the Occupational Safety and Health Administration (OSHA) (see subpar. 9g).

7. Availability of Most Advanced HIV Testing Technologies

- a. The PHS guidelines on evaluation and testing of exposure source should be followed when evaluating for possible HIV infection (see subpar. 9a).
- b. The most advanced and rapid HIV detection technologies should be made available (see subpar. 9h). Consideration should be given to using rapid HIV detection tests so that source patients' HIV status can be determined as quickly as possible.
- c. In addition to the HIV antibody blood test, the direct HIV detection test, as well as the rapid tests such as urine antibody and oral tests that have the highest degree of sensitivity and specificity, should be made available in appropriate situations along with appropriately trained technicians to perform the test(s).

8. Process Integrity Issues

- a. The exposed HCW should never be the one to approach or counsel the source patient about HIV testing.
- b. An appropriately trained person should obtain the consent for HIV testing of the source patient, or the HCW, and conduct the counseling and post-exposure management of the exposed HCW. The post-exposure prophylaxis, management and treatment of the exposed HCW, may best be directed by a multidisciplinary team of VA providers who are trained in issues dealing with occupational exposures.
- c. A facility multidisciplinary team should be available for consultation during the off-shifts and non-administrative hours.

9. References

- a. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and HIV and Recommendations for Post-exposure Prophylaxis. Morbity and Mortality Weekly Report (MMWR) 2001;50 (No. RR-11):1-43. (Web address: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm)
 - b. VHA Handbook 1004.1.
 - c. Title 38 CFR Section 17.32
- d. Veterans' Benefits and Services Act of 1988, Public Law No. 100-322, Section 124, 102 Stat. 487 (1988) (38 U.S.C. Section 7333).
 - e. Title 38 CFR Section 1.460-1.496.
 - f. Title 38 U.S.C. Section 7332.
- g. Office of General Counsel Advisory Opinion VADIGOP 6-8-88. Informed Consent for Testing and Autopsies for AIDS. June 8, 1988.
 - h. VHA Manual M-1, Part 1, Chapter 9, Release of Medical Information.
- g. Occupational Safety and Health Administration's Regulation on Bloodborne Pathogens. (29 CFR Section 1910.1030, Bloodborne pathogens).
- h. Holodniy M. "Establishing the Diagnosis of HIV Infection" <u>AIDS Therapy</u>. Dolin, Masur & Saag Eds. Churchill Livingstone Publisher, 1999.
- **10.** Questions may be referred to Abid Rahman, Director, Government Liaison, with the Public Health Strategic Health Care Group (132/13B), at 202-273-8468 or e-mail to: abid.rahman@mail.va.gov.

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